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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,577	07/22/2003	Raymond Pratt	109536.183	6543
24395	7590	09/23/2005	EXAMINER	
WILMER CUTLER PICKERING HALE AND DORR LLP THE WILLARD OFFICE BUILDING 1455 PENNSYLVANIA AVE, NW WASHINGTON, DC 20004			COOK, REBECCA	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 09/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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**Office Action Summary**

Application No.

10/623,577

Applicant(s)

PRATT, RAYMOND

Examiner

Rebecca Cook

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/22/03, 9/4/03, 6/14/04, 7/1/05.</u> | 6) <input type="checkbox"/> Other: ____.  |

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### **DETAILED ACTION**

Claims 1-35 are pending and examined.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10, 14-19, 21 are rejected under 35 U.S.C. 102(b) as being anticipated by WO98/43675. WO98/43675 (see abstract CA129:293908) discloses an oral drug solution containing donepezil-HCl, a sweetener and povidone in water and that it masks unpleasant tastes inherent in the drug.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO98/43675 for the reasons given above.

Claims 1-9, 11-13, 20 and 22-35 differ over WO98/43675 in reciting a solution, additional agents and amounts. However, once a palatable oral composition is known, it is within the skill of the artisan to determine optimum amounts and additional agents, all of which are conventional in the art. Additionally, no unobviousness is seen in the

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solutions and other oral liquid formulations of claims 1-9 and 24-35. It is noted that in the instant specification (page 28, lines 19-26) solutions, emulsions and suspensions are recited as just one formulation in a list of liquid oral forms for administration.

Claims 22-23 differ over WO98/43675 in reciting specific enantiomers. However, in the absence of a showing of unexpected results, an enantiomer is rendered unobvious once it is known as a racemic mixture.

### **Other Art of Interest**

WO00/12135, corresponding to US 6,576,677, published March 9, 2000, teaches (examples, claims) an oral composition comprising donepezil in the instant amounts and having the instant formulations.

### ***Information Disclosure Statement***

Written Opinion for International Application and International Search Report were not considered because they are not publications under <sup>37</sup>CFR 1.98. The following documents were not received or in the Parent Applications and were not considered: WO 97/46527, WO 91/66096, WO 98/39000, JP 4-21670, JP-187674, Diagnostic and Statistical Manual of Mental Disorders, Mendez et al and Hasegawa et al.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (571) 272-0571. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Renee Jones (571) 272-0547 in Customer Service.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The official fax number is 571-273-8300.

Rebecca Cook

A handwritten signature in cursive script, appearing to read 'Rebecca Cook', written in black ink.

Primary Examiner  
Art Unit 1614

September 19, 2005